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**CERTIFICATE**

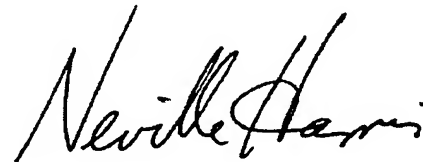
This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 23 August 1999 with an application for Letters Patent number 337387 made by SIMON PETER CLARK.

Dated 6 September 2000.

**PRIORITY  
DOCUMENT**

SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)



Neville Harris  
Commissioner of Patents



337387

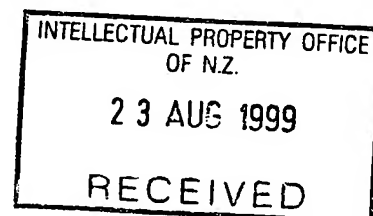
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NEW ZEALAND  
PATENTS ACT, 1953

**PROVISIONAL SPECIFICATION**

**A DEVICE FOR INHIBITING USE OF NON-PROPRIETARY CONSUMABLES**

I, Simon Peter CLARK, a New Zealand citizen of 21 Waiatarua Road, Remuera, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:



This invention relates to the use of an article identifier, particularly though not solely, for inhibiting the use of non proprietary consumables.

In the scientific field there are a number of applications where manufacturers initially sell scientific equipment on the basis that they will subsequently continue to sell consumables in relation to and for use with that equipment. However there are a number of instances where other parties have subsequently entered the market and produced a variant on the proprietary consumables. This raises a number of issues for which it may be desirable that the proprietor be able to inhibit the use of any such unauthorised consumables.

Generally, the proprietor has no control over the quality of any of the consumables sold by its competitors. Thus in particularly critical applications such as medical equipment or chemical analysers where quality assurance of the entire system is critical, the use of non proprietary consumables may reduce the level of confidence in quality, and possibly even safety, of the equipment used. Therefore from the proprietor's perspective it would be desirable that the integrity of the equipment is preserved and to this end that the use of non proprietary consumables be inhibited.

It is an object of the present invention to provide an article identifier which goes some way towards meeting the above-mentioned desideratum or which will at least provide the public with a useful choice.

In a first aspect the present invention may be broadly said to consist in an apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,  
sensing means associated with said scientific apparatus, and

control means which inhibits the operation of said scientific apparatus unless said sensing means detects said identification means.

Preferably said control means includes a processor programmed with a stored program and either said identification means or said control means includes one or more registers, said program when executed on said processor causes said control means to

carry out the steps of:

- 1) establishing communication between said control means and said identification means and if this is not successfully completed, halting the program and returning a negative result;
- 2) interrogating one or more registers in said identification means or said control means and using the information contained therein to predict whether the component said identification means is associated with, is in an acceptable state for use with said scientific apparatus and if not, halting the program and returning a negative result;
- 3) halting the program and returning a positive result.

Preferably said program is executed every time said scientific apparatus is operated and wherein said control means will inhibit the operation of said scientific apparatus unless a positive result is returned from said program.

Preferably said identifier means comprises an interrogatable radio frequency identification device.

Preferably said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

Alternatively said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

In a further alternative said scientific apparatus comprise intra vascular diagnostic equipment adapted for internal diagnosis and treatment of a patient, and said disposable or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

In a further alternative said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

In a further alternative said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

In a further alternative said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient and said disposable or consumable components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

In a second aspect the present invention may be broadly said to consist in a chemical analyser comprising:

a reagent dispenser including a reagent vial,  
identification means associated with said reagent vial,  
sensing means associated with said chemical analyser, and  
control means which inhibits the operation of said chemical analyser unless said sensing means detects said identification means.

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In a third aspect the present invention may be broadly said to consist in a medical laser system for treating a patient comprising:

laser generating means,  
optical means for conveying said laser from said laser generating means to said patient,  
identification means associated with said optical means,  
sensing means associated with said medical laser system,  
control means which inhibits the operation of said medical laser system unless said sensing means detects said identification means.

In a fourth aspect, the present invention may be broadly said to consist in an apparatus for preventing use of unauthorised disposable or consumable components and allowing use of authorised disposable or consumable components in conjunction with scientific apparatus comprising:

identification means associated with said authorised disposable or consumables,  
sensing means associated with said scientific apparatus, and  
control means programmed with stored instructions comprising the steps of:

- 1) establishing communication between said control means and said identification means and if this is not successfully completed, inhibiting the operation at said scientific apparatus and halting.
- 2) predict whether the component said identification means is associated with,

is in an acceptable state for use with said scientific apparatus based on information stored in either said identification means or said control means and if not, inhibiting the operation of said scientific equipment and halting.

3) permitting the operation of said scientific equipment.

Preferably said identifier means comprises an interrogatable radio frequency identification device.

Preferably said scientific apparatus comprises a chemical analyser and said disposable or consumable components comprise at least one reagent.

Alternatively said medical or analytical apparatus comprises a medical laser system and said disposable components comprise optical fibres.

In a further alternative said scientific apparatus comprise intra vascular diagnostic ~~equipment adapted for internal diagnosis and treatment of a patient, and said disposable~~ or consumable components comprise catheter means which in use conveys a portion of said vascular diagnostic equipment into the vascular cavity of said patient.

In a further alternative said scientific apparatus comprise tissue processing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise fixative fluids or solvents which in use fix the said tissue to said slide.

In a further alternative said scientific apparatus comprise tissue analysing equipment including slide means adapted to support said tissue in use and said disposable or consumable components comprise slide staining means which are adapted to in use stain the said tissue.

In a further alternative said scientific apparatus comprise haemodialysing equipment adapted to filter the blood of a patient and said disposable or consumable components comprise a dialysis unit including a filter which in use removes waste products from said patient's blood which is circulated by said haemodialysing equipment.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be

incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of the present invention according to the first preferred embodiment,

Figure 2 is a flow diagram of the control strategy according to the present invention

Figure 3 is a block diagram of the electronic apparatus according to the present invention,

Figure 4 is a block diagram of the present invention according to the second preferred embodiment,

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The present invention provides a means for controlling the use of consumable or disposable components for use with scientific equipment. In the preferred embodiment the present invention will prohibit operation of the scientific equipment where the consumable or disposable components are not authorised and therefore do not include an electronic identifier. This system has flexibility in that where such components may be used several times before being discarded, the electronic identifier can keep track of how many times each component has been used and when depleted it will bar operation of the device until the component in question is replaced with a new authorised component.

One application where the present invention is of particular advantage is chemical analysers which use a consumable chemical reagent each time particular substance is tested for the presence or absence of a particular chemical. A chemical analyser such as would be appropriate for use with the present invention is shown in Figure 1 . It is seen that the analyser 110 comprises a number of generic components including the reagent dispenser 112, a carousel 114, test vessels 116 and a testing and analysis stage 118. The reagent dispenser 112 includes a removable vial 120 which is filled with bulk reagent 122.

In the preferred embodiment of the present invention the vial 120 includes an electronic identifier 124 integrated into the neck 126. It will be appreciated however that the electronic identifier 124 could be located anywhere in association with the vial 112 and in fact could be of the form of a smart card type device independent of the vial which

is recharged when the reagent vial is refilled from a authorised stockist.

### **Control Methodology**

Whatever the application, the interrogation of the identifier to complete the authorisation process will follow an essentially generic path. Figure 2 illustrates this process in the form of a flow diagram. Whenever the apparatus in question starts up the authorisation algorithm runs through and if successful then the operation of the apparatus proceeds.

The first step is the application of the RF field 150 to initiate communications with the identifier. It will be appreciated that the content of this first step is dependent on the method of identification that is used. The RF field is applied for a set period 152 waiting for a response from the identifier. If one is not received within this period, the algorithm ~~halts 154 with a negative result. If communication is established, the first register in the~~ identifier is interrogated 156. This contains a date value relating to the device's "use by" date. If the "use by" date has passed, the device is deemed expired, and the algorithm halts 158 with a negative result. If not, the second register is interrogated 160, which contains information on the remaining use allowed for the device. If no use remains the device is deemed depleted and the algorithm halts 162 with a negative result. If there is remaining use, the use counter is decremented by one or more units 164, and the algorithm halts with a positive result 166.

It will be appreciated that the operation of the apparatus is conditional on the return of a positive result from the authorisation algorithm. Further where there is a negative result specific error codes could be returned allowing messages to be displayed to the user informing them of the problem and possible solutions.

### **Component Identifier**

In the preferred embodiment of the present invention the identifier is in the form of a electronic radio frequency identification (RFID) interrogatable device. RFIDs use wireless communication to transmit and receive data from a transceiver to a transponder and where the transponder itself may only be readable or read writable where instructions are to be passed in both directions. Referring now to Figure 3 the transceiver 170, including an antenna 172 or a coil, is a preferred embodiment of the present invention integrated with the chemical analyser in closer proximity to where the reagent vial is



situated. The transceiver 170 is controlled by either a separate microcontroller 174 specifically for the authorisation process or where the analyser has its own micro controller it can be controlled by that. However the transceiver is controlled, there will still need to be some form of data link 176 to allow the overall operation of the analyser to be inhibited if the authorisation process is not correctly completed.

The transponder 178 or RF tag as they are sometimes known will be located somewhere on the reagent vial 180 as already described. There are a number of methods of transferring information from the transponder to the transceiver. In the preferred embodiment for the present invention, radio frequency propagation 180 in the range 10-15 MHZ is used for communication between the transceiver and transponder. This provides access to well-proven technology on a mass produced scale and a good data transfer rate.

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~~It will be appreciated that while one method is described for the preferred embodiment of~~  
the present invention, many other methods will be equally possible eg: infrared or laser signalling, inductive coupling, capacitive coupling, electrostatic methods, direct electrical connection and, for that matter, a simple device such as barcode and scanner could be utilised in variations on the present invention.

The previously described algorithm is executed on the apparatus controller 174, which in turn controls the dispensing mechanism which may in turn activate a valve 184 to control the reagent dispensation.

The transponder itself may be embodied in any one of a number of forms. It may simply include an authentication code to ensure it has been sourced from an authorised source or may also include one or more registers which store any manner of information in relation to the apparatus. As indicated in the foregoing description, information on the use-by date of the current stock of reagents might be stored in order to ensure that once it has passed this expiry date it is prevented from being used. Further, such registers may be used to store the amount of reagent used to date and therefore to indicate how much reagent remains and therefore when the file is empty.

### **Further Applications**

As already mentioned the present invention is applicable to scientific equipment in general. Another application in which such a device would be particularly useful is with disposable medical articles. One example is fibre optic strands used with a surgical laser

system, where the fibres are inserted internally into the body. It will be appreciated however that many similar applications exist and this application is only given by way of example.

Referring now to Figure 4, a surgical laser system is illustrated which is adapted for use with the present invention. The laser beam itself is initiated in the generator module 200 which is controlled by the control and display module 202. The laser beam is channelled through a fibre optic strand 204 which is protected with an outer semi-rigid sheath. The internal positioning of the strand 204 within a patient 206 is controlled by a hand held controller 208 which adjusts both lateral and proximity positioning of the open end of the strand 204.

The strand 204 itself, as it is exposed to bodily fluids, must either be disposed of ~~and replaced after every use, or thoroughly disinfected~~. Quality and safety demands necessitate that disposal is the preferred alternative.

As previously mentioned, it is preferable that where disposable components are to be used they be of dependable levels of quality and safety. To this end, the present invention provides a means of ensuring only components from authorised sources can be used with the surgical laser system.

As with applications in the chemical analyser previously described, an identifier is associated with each disposable component. In practice, an identifier is integrated into the connector 210 at the point where the strand is attached to the generator module 200.

Using the method previously described, the operation of the laser is conditional on the correct authorisation process being completed between an interrogator integrated in the generator module 200 and the identifier associated with the strand 204.

Another application might be where heart disease is investigated and treated with catheters that are inserted into the vascular system and directed into the heart. In many cases the catheters carry electrical conductors that allow the electrical events associated with cardiac contraction to be observed and recorded by equipment (for example an electrocardiograph). In some cases the catheters carry conductors or radio frequency wave-guides that allow electromagnetic energy to be conveyed to the heart for treatment purposes. The present invention might be incorporated within the electrocardiograph or

within a source of rf energy in order to inhibit the reuse of disposable catheters.

In the case of processing of tissue specimens in automated processors, a variety of fixative fluids and solvents are employed so that they can subsequently be transformed into microscopic slides. The present invention might be incorporated within the processor and the various fluid containers to control the use of non-proprietary solvents.

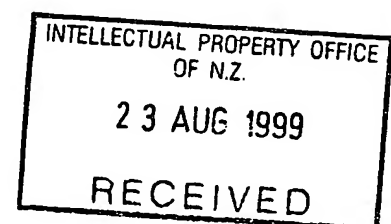
In a similar vein a variety of biological specimens, including tissue, blood, and other body fluids are applied to a glass substrate ("slide") and examined microscopically after the specimens have been stained. Various devices exist to stain the slides. In one application of the present invention the device could be incorporated within the automated stainer and the containers that store the stains to control the use of non-proprietary stains or reagents.

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Patients with renal disease may be treated with extra-corporeal haemodialysis.

Haemodialysers pump blood from the patient through a dialysis unit that removes waste products from the blood, after which the blood is returned to the patient. The dialysis units are frequently designed to be disposable, but in some cases have been cleaned and reused, with subsequent injury to the patients. The present invention could be incorporated within the haemodialyser to inhibit reuse.

DATED THIS 20<sup>th</sup> DAY OF August 1999  
A.J. PARK & SON  
PER *[Signature]*  
AGENTS FOR THE APPLICANT



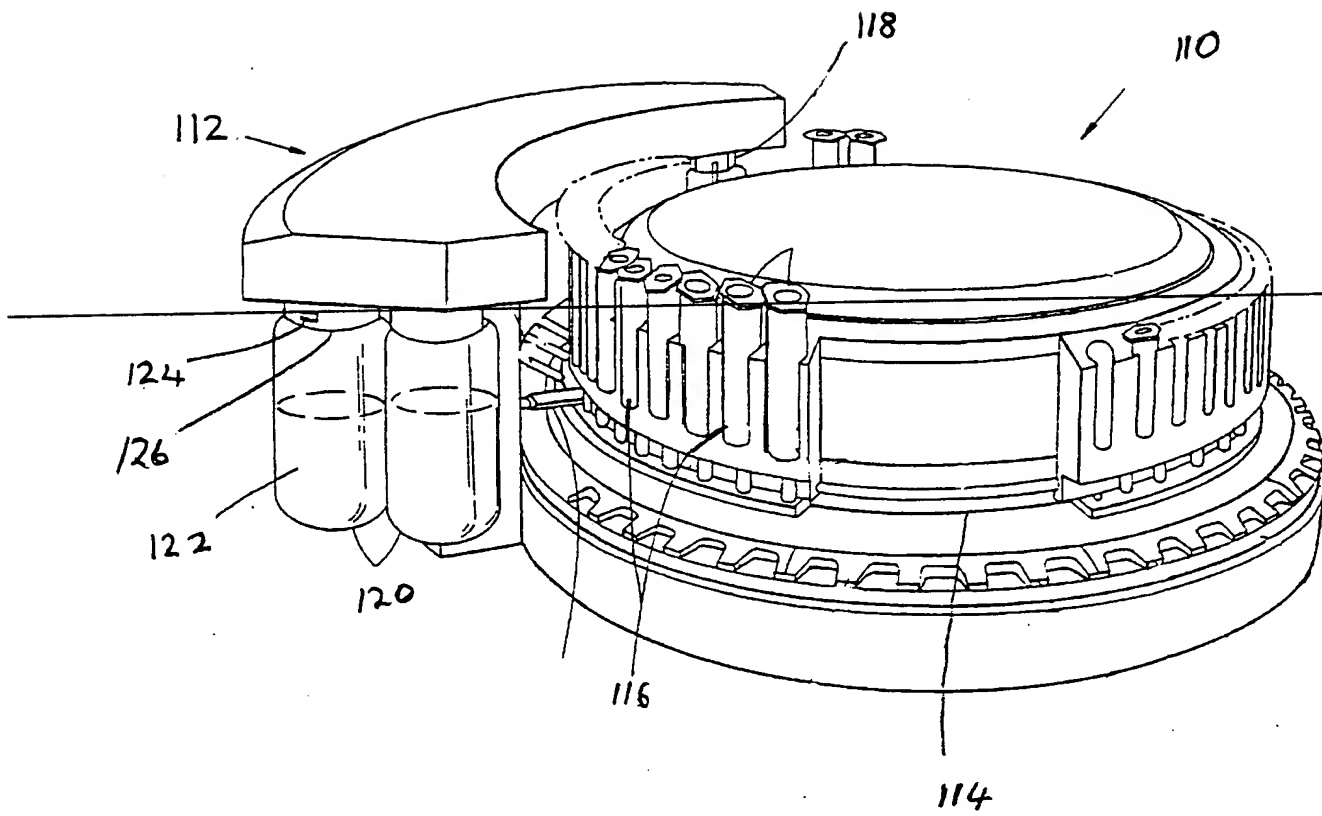


FIGURE 1

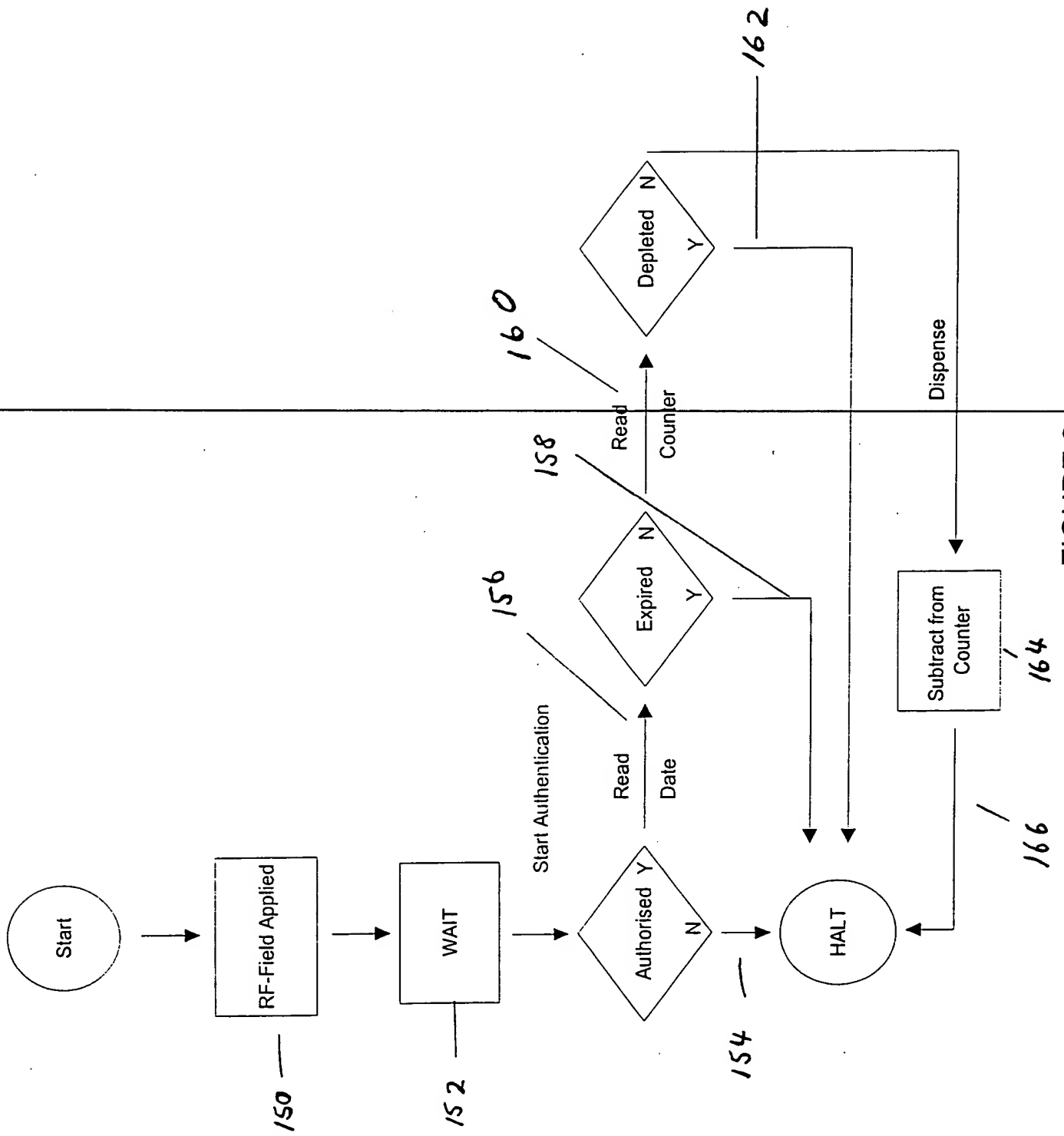


FIGURE 2

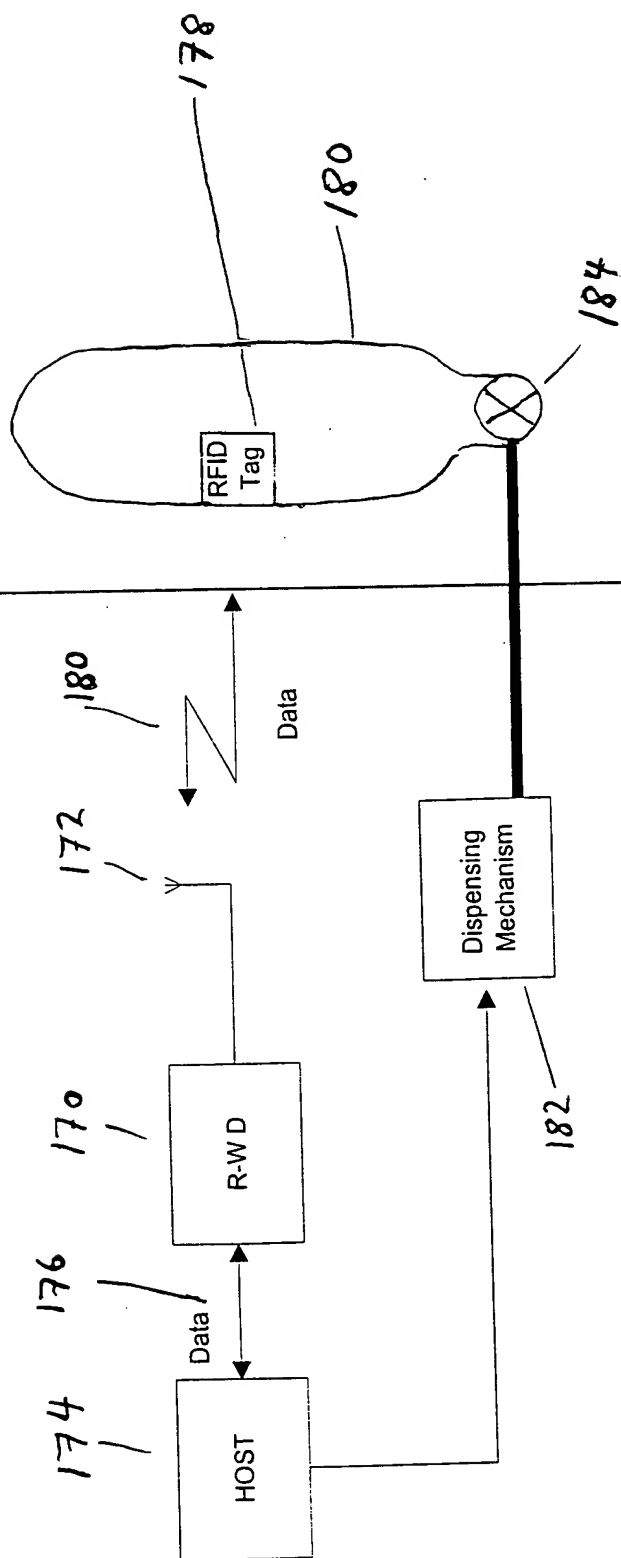


FIGURE 3

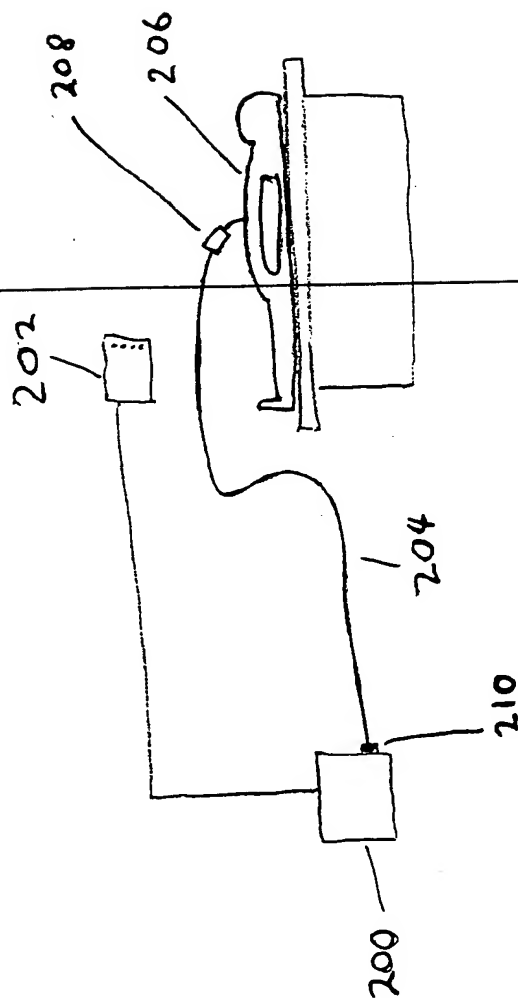


FIGURE 4